

**REMARKS**

**I. Amendments**

The specification has been amended to correct a typographical error.

Claims 14-26 have been amended without prejudice or disclaimer to recite "A method of treating seborrheic dermatitis." Support for this amendment can be found throughout the application as originally filed. Applicants make this amendment to affirm that their claimed methods treat the disease seborrheic dermatitis, and not just a symptom of seborrheic dermatitis such as dandruff.

Claims 14-29 are pending, with claims 14, 19, 24, 25, and 26 being independent.

**II. Claim Rejection Under 35 U.S.C. § 112, ¶ 1**

In the Office Action dated June 29, 2004, claim 24 has been rejected for allegedly lacking written description support for the claim term "one phase." Office Action at 2. Applicants respectfully disagree with this rejection.

"To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." M.P.E.P. § 2163(I) (citations omitted). Applicants respectfully contend that their specification satisfies this test as to "one phase" compositions.

The specification teaches the unique water solubility that allows for single phase compositions. "Compared with ketoconazole, the compounds used according to the invention furthermore have very crucial advantages with respect to their processing possibilities in pharmaceutical preparations." Specification at 2, II. 14-16. Unlike

ketoconazole, which can be solubilized by dissolving in an oil phase, for example, many of the 1-hydroxy-2-pyridones of Applicants' formula (I) need not be dissolved in an oil phase. "On account of their solubility in water, alcohols and aqueous-alcoholic solutions, the preparation of hair lotions and transparent gel preparations is possible without problems." *Id.* at 2, ll. 16-19. Those solutions and transparent gels teach the single phase nature of some of the compositions useful in the method of claim 24, because the skilled artisan would understand that multiply phased compositions such as emulsions usually are not "solutions" nor transparent.

### **III. Claim Rejections Under 35 U.S.C. § 103**

Claims 16-29 (and presumably claims 14 and 15) have been rejected under 35 U.S.C. § 103 as allegedly being obvious over *Lange* (U.S. Pat. No. 5,132,107) alone, or alternatively in view of *Durrant et al.* (U.S. Pat. No. 4,699,924) or *Saint-Leger* (U.S. Pat. No. 5,650,145). Applicants respectfully disagree with these rejections.

Nearly identical rejections of similar claims over the same prior art have been vacated by the Board of Patent Appeals and Interferences in the parent application. See Decision on Appeal in Application No. 09/077,194, at 2 (copy enclosed for the Examiner's convenience). Accordingly, Applicants respectfully request that the Examiner withdraw the pending rejections.

The Board applied new grounds of rejections, centered on *Saint-Leger*. See Decision at 7-14. Applicants respectfully contend that those new rejections should not be applied here, at least because Applicant's claim amendment above obviates a claim

construction reading on treating a symptom of seborrheic dermatitis rather than treating the disease.

Applicants respectfully refer the Examiner to two opinions strongly suggesting that the new rejections should not be applied to the amended claims. See *Jansen v. Rexall Sundown Inc.*, 342 F.3d 1329, 68 U.S.P.Q.2d 1154 (Fed. Cir. 2003); and *Rapoport v. Dement*, 254 F.3d 1053, 59 U.S.P.Q.2d 1215 (Fed. Cir. 2001). In both cases, claimed inventions relating to treating diseases were challenged with prior art that taught treating only symptoms of the diseases. In both cases, the Federal Circuit panel rejected the notion that treating a symptom rendered obvious the treatment of the disease.

The *Jansen* court described *Rapoport* as follows:

On appeal we gave weight to the ordinary meaning of the preamble phrase “for treatment of sleep apneas,” interpreting it to refer to sleep apnea, *per se*, not just “symptoms associated with sleep apnea.” . . . Rapoport argued that the count was unpatentable on the ground that a prior art reference disclosed that a form of the compound recited in the claim could be administered, not for treatment of sleep apnea itself, but for treatment of anxiety and breathing difficulty, a symptom of apnea. . . . We rejected that argument stating, “There is no disclosure in the [prior art reference that the compound] is administered to patients suffering from sleep apnea *with the intent to cure the underlying condition*.” . . . Thus, the claim was interpreted to require that the method be practiced with the intent to achieve the objective stated in the preamble.

*Jansen*, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1157-58 (*citing Rapoport*, 254 F.3d at 1059, 59 U.S.P.Q.2d at 1219).

The court in *Jansen* reached a similar result. “Just as in *Rapoport*, it is natural to interpret the nearly parallel language in the '083 patent claims in the same way.”

*Jansen*, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1158. Therefore, treating a symptom does not teach or suggest a method for treating an underlying condition or disease.

The Board considering Applicants' parent application concluded that the appealed claims read on alleged prior art that teaches treating only alleged symptoms of seborrheic dermatitis. See Decision at 8. Notably, the Board did not conclude that any of the alleged prior art teaches or suggests a method of treating seborrheic dermatitis *per se*. See Decision. Accordingly, Applicants' claimed methods of treating seborrheic dermatitis should not be rejected on teachings of treating mere symptoms found in the alleged prior art. Just as in *Jansen* and *Rapoport*, *Saint-Leger's*, *Lange's*, and *Durrant's* methods of treating symptoms such as dandruff do not teach or suggest treating seborrheic dermatitis.

#### **IV. Provisional Double Patenting Rejection**

Claims 16-29 (and presumably claims 14 and 15) are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over the claims of copending Application No. 09/077,194. Office Action at 7. Applicants respectfully disagree with this rejection.

Because the copending Application has not been allowed, Applicants respectfully request that this rejection be held in abeyance until such time as claims have been allowed in one of the applications. At that time, Applicants will have the information necessary to determine whether or not to file a Terminal Disclaimer.

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

A Petition for Extension of Time (One Month) and fee therefor accompany this Amendment. Please grant any further extensions of time required to enter this Amendment and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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**Attachments:**

**Decision on Appeal** in parent Application No. 09/077,194.